FDA

MAUDE Adverse Event Report: EPIC EPIC EHR SOFTWARE

EPIC EPIC EHR SOFTWARE

Back to Search Results

Event Date 06/09/2017
Event Type Injury
Event Description

Pt presented to emergency ward with delirium and leukocytosis. Extensive neurological eval was undertaken. It was negative. The chest radiograph with reported late, and the report came back silently into the radiograph silo, as pneumonia, but no one saw the report. There was not any notice or warning that a new report had been generated. In addition, the ehr device uses elaborate system to generate a complete history and physical exam report. There was no way that the lungs were "clear" as stated by the doctors (er and attending) using the canned language of the ehr macro/template when the pt had bilateral pneumonia. The treatment with antibiotics was delayed by 20 hours. This case raises important issues that have been wrought by ehr devices that have not had any vetting for safety, unstability, and efficacy, and remain free of after market surveillance. Reports of all types get deposited into their respective silos silently, and no one knows the results for hours whether they are good or bad. Care is delayed with frequent life threatening consequences. The ehr device enables elaborate reports of examinations, that often are not done, with one swift click of the mouse. Basically, these are fake exams and histories.

Search Alerts/Recalls[22]

New Search | Submit an Adverse Event Report[23]

Brand Name EPIC EHR
Type of Device SOFTWARE
Manufacturer *(Section D)* EPIC
Verona WI 53593
MDR Report Key 6636342
Report Number MW5070360
Device Sequence Number 1
Product Code JQP[24]
Report Source Voluntary
Reporter Occupation Physician
Report Date 06/10/2017
***1* Device Was Involved in the Event**
***1* Patient Was Involved in the Event**
Date FDA Received 06/10/2017
Is This An Adverse Event Report? Yes
Is This A Product Problem Report? Yes
Device Operator Health Professional
Was Device Available For Evaluation? Yes
Is The Reporter A Health Professional? Yes
Was the Report Sent to FDA?
Event Location No Information
Was Device Evaluated By Manufacturer?
Is The Device Single Use?
Is this a Reprocessed and Reused Single-Use Device? No
Type of Device Usage

Patient TREATMENT DATA
Date Received: 06/10/2017 Patient Sequence Number: 1

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
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8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
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18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm
23. https://www.accessdata.fda.gov/scripts/medwatch/
24. ../cfPCD/classification.cfm?start_search=&ProductCode=JQP

Page Last Updated: 01/31/2019

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